September 15, 2021

Fox Hollow Technologies
Melissa Murphy
740 Bay Road
Redwood City, California 94063

Re: K071826
Trade/Device Name: The Rinspirator
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy catheter
Regulatory Class: Class II
Product Code: QEZ, KRA

Dear Melissa Murphy:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated November 9, 2007. Specifically, FDA is updating this SE Letter because FDA has created a new product code to better categorize your device technology.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Gregory O'Connell, OHT2: Office of Cardiovascular Devices, (301) 796-6075, Gregory.Oconnell@FDA.HHS.gov.

Sincerely,

Gregory W. O'connell -S
Digitally signed by Gregory W. O'connell -S
Date: 2021.09.15 10:21:28 -04'00'

Gregory O'Connell
Assistant Director
Plaque Modification Devices Team
DHT2C: Division of Coronary and Peripheral Intervention Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 0 9 2007

FoxHollow Technologies, Inc.
c/o Ms. Melissa S. Murphy
Regulatory Affairs Manager
740 Bay Road
Redwood City, CA 94063

Re: K071826
Trade/Device Name: The Rinspirator
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy catheter
Regulatory Class: Class II
Product Code: DXE
Dated: October 17, 2007
Received: October 19, 2007

Dear Ms. Murphy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. INDICATIONS FOR USE STATEMENT

510(k) Number if known: K071826

Device Name: The Rinspirator

The Rinspirator is intended to infuse physician specified fluid and remove/aspirate fluid, fresh, soft emboli and thrombi from the coronary and peripheral vasculature.

Prescription Use X (Per 21 CFR 801 Subpart D)

AND/OR

Over-the-Counter Use _____ (Per 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K071826

5. 510(K) SUMMARY

510(K) SUMMARY

Device Name	The Rinspirator®
Classification Name:	Embolectomy Catheter 21 CFR §870.5150, Class II
Product Code:	DXE
Common and Usual Name:	Embolectomy Catheter
Proprietary Name:	The Rinspirator®

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Predicate Device

The Rinspiration Catheter System (K062275), currently marketed by FoxHollow Technologies, Inc. (Redwood City, CA).

Summary

This summary of Special 510(k) safety and effectiveness is being submitted in accordance with requirements of SMDA 1990.

The Rinspirator is intended to infuse physician specified fluid and remove/aspirate fluid, fresh, soft emboli and thrombi from the coronary peripheral vasculature. The Rinspirator consists of a catheter and a hand-held unit with accessories. The Rinspirator Catheter is a multi-lumen, rail configuration catheter to dispense an infusible fluid. The central lumen of the catheter is used for aspiration. The Rinspirator is provided sterile for single-use. The system is sterilized by Ethylene Oxide (ANSI/AAMI/ISO 11135), including limits for Ethylene Oxide residuals and validated to a sterility assurance level (SAL) of 10^{-6}. The device is biocompatible per ISO-10993-1.

The only difference between the cleared Rinspiration Catheter System and The Rinspirator is the lubricious coating on the external surface of the catheter shaft. The previously cleared device is coated using a silicone based material, which is being replaced with a hydrophilic coating, consisting of a primer and topcoat in an ethanol solvent base, and is cured using UV light.

With the exception of the coating, The Rinspirator is substantially equivalent in materials of construction, design, intended use, and safety and efficacy to the predicate device. The subject device was shown to have substantially equivalent performance when compared to the predicate device. The Rinspirator with coating modifications is considered substantially equivalent to the Rinspiration Catheter System (K062275).

Contact
Sridevi Sheshadri
Clinical Research Associate
FoxHollow Technologies, Inc.
740 Bay Road
Redwood City, CA 94063
Main Tel (650) 421-8400

Date
June 26, 2007